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Research paper

Valve-in-valve TAVI and risk of coronary obstruction: Validation of the VIVID classification

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ABSTRACT

Background: The Valve-in-Valve International Data (VIVID) registry proposed a simplified classification to assess the risk of coronary obstruction during valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) based on preprocedural multi-detector computed tomography (MDCT). We investigated the validity of the VIVID classification in patients undergoing ViV-TAVI for degenerated bioprostheses.

Methods: Patients undergoing ViV-TAVI for degenerated bioprostheses were prospectively included in this study. The risk of coronary obstruction among patients treated with stented valves was retrospectively evaluated based on anatomical assessment on pre-procedural MDCT.

Results: Among a total of 137 patients that underwent ViV-TAVI between August 2007 and June 2021, 109 patients had stented, sutureless, or transcatheter degenerated bioprosthesis of which 96 (88%) had adequate MDCT data for risk assessment. High-risk anatomy for coronary obstruction (VIVID type IIB, IIIB, or IIIC) in either the left or right coronary artery was observed in 30 patients (31.3%). Of the 30 patients with high-risk anatomy, coronary protection using wire protection or BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) was performed in 3 patients (10.0%). Three patients treated with stentless valves and one patient treated with a stented valve with externally mounted leaflets had coronary obstruction. None of the patients with high risk anatomy according to MDCT had coronary obstruction even without coronary protection.

Conclusions: Coronary obstruction occurred in none of the patients classified as high-risk patients according to the VIVID classification despite the absence of coronary protection. Refined tools are required to assess the risk of coronary obstruction.

Clinical trial registration: <https://www.clinicaltrials.gov>. NCT01368250.

1. Introduction

Valve-in-valve transcatheter aortic valve implantations (ViV-TAVI) are expanding as the new standard of care for the treatment of degenerated bioprostheses.^{1–8} In the current guidelines for the management of valvular heart disease, ViV-TAVI assumes a class 2a level of evidence B-NR recommendation.^{9,10} Coronary obstruction is the most feared

complication of ViV-TAVI,¹¹ and there is a growing demand to establish a standardized risk assessment method for the prevention of coronary obstruction in patients undergoing ViV-TAVI.¹²

Prior studies have suggested several anatomical risk factors for coronary obstruction during ViV-TAVI and have proposed techniques to prevent this dreadful complication.^{13–15} BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary

Abbreviations: AS, aortic stenosis; BASILICA, bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; ViV-TAVI, valve-in-valve transcatheter aortic valve implantation; VIVID, Valve-in-Valve International Data.

Tweet: “Coronary obstruction is a dreadful although rare complication of TAV-in-SAV. VIVID classification overestimates risk of coronary obstruction in stented bioprostheses. Refined tools for risk assessment are required, particularly for patients treated with stentless valves.”

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artery obstruction) is a recently proposed transcatheter procedure which lacerates the aortic valve leaflets before TAVI, allowing them to splay to the sides after transcatheter heart valve deployment and, therefore, maintaining coronary perfusion. Although the feasibility of the technique has been shown in a dedicated study, appropriate patient selection for the technique, including anatomical considerations, remains largely unknown.¹⁴ Recently, the Valve-in-Valve International Data (VIVID) registry proposed a simplified classification based on preprocedural multi-detector computed tomography (MDCT) to assess the risk of coronary obstruction during ViV-TAVI in stented bioprostheses and the possible need for BASILICA.¹⁶ In the present study, we aimed to investigate the validity of the VIVID classification in patients undergoing ViV-TAVI based on data from a prospective TAVI registry.

2. Methods

2.1. Study design and population

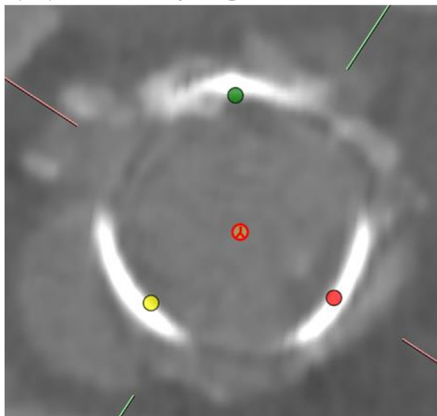
All patients undergoing TAVI at Bern University Hospital, Bern, Switzerland, are consecutively recorded in a prospective institutional database as part of the SwissTAVI registry which is mandated by the Swiss health authorities (registered at clinicaltrials.gov with NCT01368250).¹⁷ The present analysis included consecutive patients that underwent ViV-TAVI between August 2007 and June 2021. Among them, patients with a stented, sutureless, or transcatheter degenerated bioprosthesis and adequate pre-procedural MDCT images were evaluated

for the risk of coronary obstruction according to the VIVID classification. The systolic phase of multi-detector computed tomography with the least motion and blooming artifact was selected. Patients implanted with stentless valves were not evaluated for the risk of coronary obstruction as these valves lack a fluoroscopic marker, and the posts are not identified on MDCT. The registry is approved by the Bern cantonal ethics committee, and patients provided written informed consent to participate.

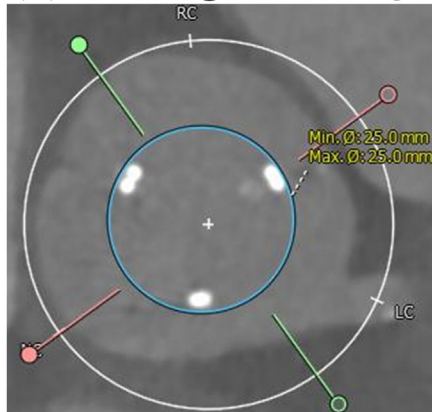
2.2. Assessment of coronary obstruction risk

The risk of coronary obstruction was retrospectively evaluated in patients with stented, sutureless, or transcatheter degenerated bioprostheses based on anatomical assessment on pre-procedural MDCT. The pre-procedural MDCT was performed as previously described. Acquired images were transferred to a dedicated workstation (3mensio Structural Heart, 3mensio Medical Imaging BV, Bilthoven, The Netherlands) and evaluated by experienced imaging specialists in a dedicated Corelab.¹⁸ The risk assessment included 1) identification of the basal ring of the bioprosthesis; 2) assessment of the length of the prosthetic posts in relation to the offtake of the coronary arteries and the height of the coronary sinus; 3) measurement of the valve to coronary ostium (VTC) distance and the valve to sinotubular junction (VTSTJ) (VTSTJ) distance. The basal ring of the bioprosthesis was identified on a transverse double oblique plane. In cases in which the coronary arteries took off below the bioprosthetic posts, VTC was measured. The VTC was assessed using a virtual cylinder with the size of the implanted

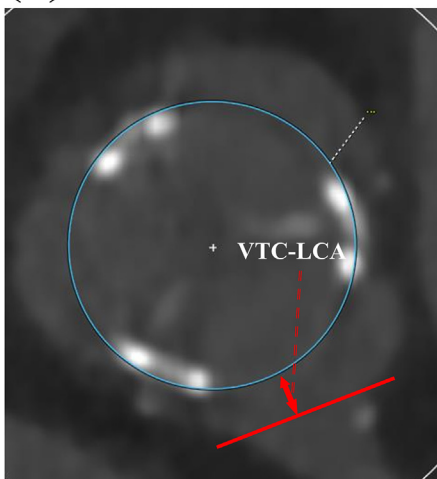
(A) Identifying the basal ring



(B) Drawing virtual ring



(C) Measurement of VTC



(D) Measurement of VTSTJ

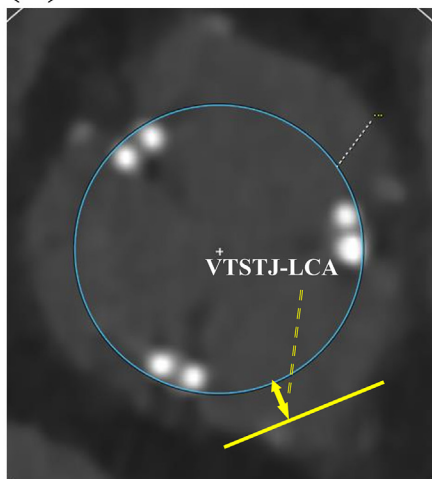


Fig. 1. Assessment for risk of coronary artery obstruction according to VIVID classification. (A) Identifying the three most basal points of the bioprosthesis. (B) Draw a circular region of interest with implanted valve-specified diameter. (C) Measurement of VTC from the virtual circle to the coronary ostium. (D) Measurement of VTSTJ from the virtual circle to the sinotubular junction. LCA = left coronary artery; VIVID = Valve-in-Valve International Data; VTC = virtual valve to coronary ostium; VTSTJ = virtual valve to sinotubular junction.

bioprosthesis. A virtual cylinder with the implanted prosthesis-specific diameter was aligned with the posts of the implanted bioprosthesis. Then, the distance between the edge of the cylinder and the coronary ostium was measured. In cases in which the prosthesis posts extended above the STJ, the VTSTJ was also evaluated (Fig. 1).^{13,19,20} Each coronary artery ostium was evaluated separately.

2.3. VIVID classification

We classified each coronary artery according to the VIVID classification as follows;

Type I: The failed bioprosthetic leaflets extend below the coronary ostia plane.

Type II: The failed bioprosthetic leaflets extend between the coronary ostium and the STJ. Type II anatomy was further classified as type IIA (VTC ≥ 4 mm) or type IIB (VTC < 4 mm) based on the VTC distance.

Type III: The failed bioprosthesis leaflets extend above the level of STJ. Type III anatomy was further classified as type IIIA (VTC ≥ 4 mm and VTSTJ ≥ 3.5 mm), type IIIB (VTC < 4 mm), or type IIIC (VTC ≥ 4 mm but VTSTJ < 3.5 mm) based on the VTC and VTSTJ distances.

Types IIB, IIIB, and IIIC are considered high risk anatomies for coronary obstruction and BASILICA is recommended to be considered to mitigate the risk (Fig. 2).¹⁶

2.4. Data collection and clinical endpoints

Baseline clinical, procedural, and follow-up data were prospectively recorded in a web-based database, held at the Clinical Trials Unit of the University of Bern, Switzerland. The decision for transcatheter heart valve type was made by the operator. Coronary protection was performed by heart team decision. Clinical follow-up data were obtained by standardized interviews, documentation from referring physicians, and hospital discharge summaries. All adverse events were systematically collected and adjudicated by a dedicated clinical event committee based on the standardized VARC definitions applicable at the time of the procedure.^{21,22}

2.5. Statistical analysis

Categorical variables are represented as frequencies and percentages. Continuous variables are presented as mean values \pm standard deviation

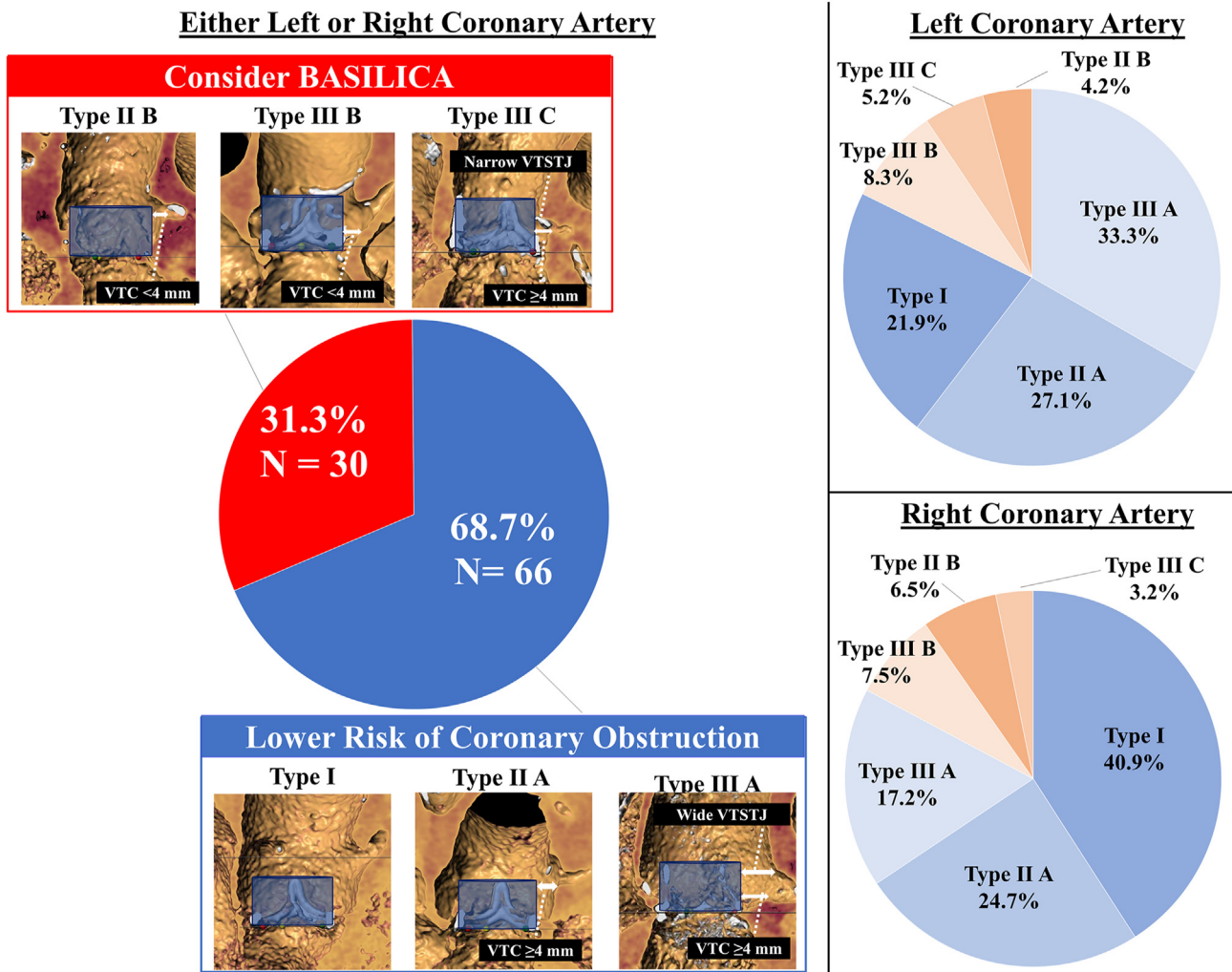


Fig. 2. Prevalence of patients at risk of coronary obstruction during ViV-TAVI. Pie chart illustrating the prevalence of patients at high and low risk of coronary obstruction (Left), the prevalence of VIVID categories in the left coronary artery (Upper Right), and the right coronary artery (Lower Right). BASILICA = bio-prosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; MDCT = multi-detector computed tomography; ViV-TAVI = valve-in-valve transcatheter aortic valve implantation; VIVID = Valve-in-Valve International Data; VTC = virtual valve to coronary ostium; VTSTJ = virtual valve to sinotubular junction.

(SD). All statistical analyses were performed using R for Windows 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Study population and baseline characteristics

Among 3201 consecutive patients enrolled in the prospective TAVI registry, 137 patients (4.3%) underwent ViV-TAVI between August 2007 and June 2021 (Fig. 3). Most of the bioprostheses were stented valves (69.4%), followed by stentless valves (20.4%), sutureless valves (5.1%), and transcatheter heart valves (5.1%). Overall, 41 patients (29.9%) were female, the mean age of the cohort was 82 ± 7 years, body mass index was 25.6 ± 4.4 kg/m², and Society of Thoracic Surgeons Predicted Risk of Mortality score was 6.9 ± 4.9 (Table 1).

3.2. Procedural characteristics

Procedural characteristics are summarized in Table 2. The reasons for ViV-TAVI were bioprosthetic valve stenosis in 53.3%, bioprosthetic valve regurgitation in 37.2%, and both a combination of stenosis and regurgitation in 9.5%. Most of the transcatheter heart valves used for ViV-TAVI were self-expanding valves (71.5%), followed by balloon-expandable valves (27.0%), and mechanically-expanding valves (1.5%). Coronary protection was performed in 13 patients (9.5%): 7 (5.1%) underwent BASILICA (5 single BASILICA for left coronary cusp and 2 double BASILICA for left and right coronary cusps), and 6 (4.4%) had wire protection. Coronary obstruction during the index procedure occurred in 4 patients (2.9%): 3 patients had a stentless valve and 1 patient had a stented valve with externally mounted leaflets.

Table 1
Baseline characteristics.

	All patients (N = 137)	Patients with assessment of the VIVID classification (N = 96)
Age, years	82 ± 7	83 ± 6
Female, n (%)	41 (29.9)	331 (34.4)
Body mass index, kg/m ²	25.6 ± 4.4	25.5 ± 4.6
LVEF, %	50.5 ± 15.3	51.1 ± 15.4
STS-PROM, %	6.9 ± 4.9	7.3 ± 5.3
Implanted bioprosthetic valve, n (%)		
Stented	95 (69.3)	84 (85.4)
Internally mounted leaflets	62 (45.3)	58 (60.4)
Externally mounted leaflets	31 (22.6)	24 (25.0)
Type unknown	2 (1.5)	2 (2.1)
Stentless	28 (20.4)	–
Sutureless	7 (5.1)	7 (7.3)
Transcatheter heart valve	7 (5.1)	5 (5.2)

Values are mean ± SD or n (%).

LVEF = left ventricular ejection fraction; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

3.3. VIVID classification

After excluding 41 patients (28; stentless bioprostheses and 13; stented bioprostheses with inadequate MDCT images to comprehensively evaluate both coronary artery ostia) and 3 right coronary arteries with inadequate MDCT images, a total of 96 patients with 189 coronary arteries [96 left coronary artery (LCA) and 93 right coronary arteries (RCA)] were assessed for the risk of coronary obstruction according to

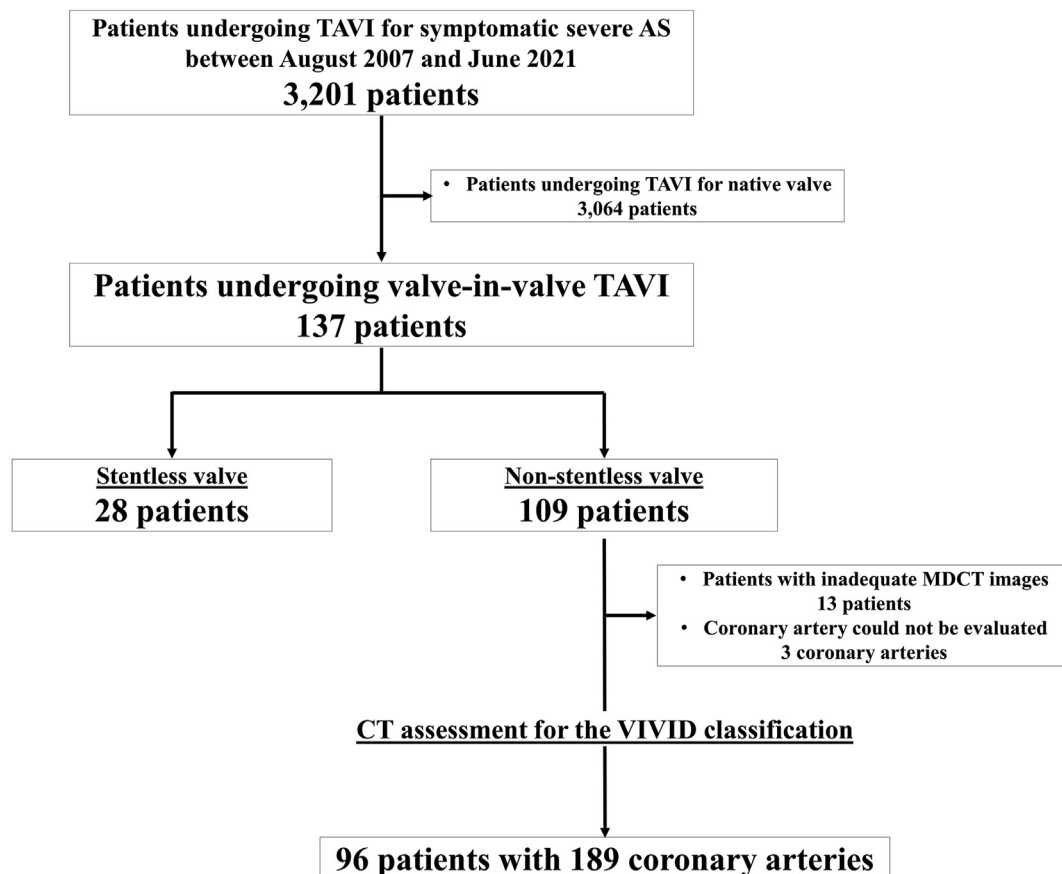


Fig. 3. Study flowchart. AS = aortic stenosis; MDCT = multi-detector computed tomography; TAVI = transcatheter aortic valve implantation; VIVID = Valve-in-Valve International Data.

Table 2
Procedural characteristics.

	All patients (N = 137)	Patients with assessment of the VIVID classification (N = 96)
Reason for ViV-TAVI, n (%)		
Bioprosthetic regurgitation	51 (37.2)	27 (28.1)
Bioprosthetic stenosis	73 (53.3)	59 (61.5)
Bioprosthetic regurgitation and stenosis	13 (9.5)	10 (10.4)
Device type, n (%)		
Balloon-expandable	37 (27.0)	25 (26.0)
Self-expanding	98 (71.5)	71 (74.0)
Mechanically-expanding	2 (1.5)	0
Device size, mm	25.8 ± 2.4	25.4 ± 2.1
Coronary protection, n (%)	13 (9.5)	7 (7.3)
BASILICA, n (%)	7 (5.1)	5 (5.2)
Wire protection, n (%)	6 (4.4)	2 (2.1)
Coronary obstruction, n (%)	4 (2.9)	0

Values are mean ± SD or n (%).

BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; ViV-TAVI = valve-in-valve transcatheter aortic valve implantation; VIVID = Valve-in-Valve International Data.

the VIVID classification. MDCT measurements are summarized in Table 3. Each coronary artery was categorized according to the VIVID classification: With respect to the left coronary artery, VIVID type I was found in 21.9%; type IIA in 27.1%; type IIB in 4.2%; type IIIA in 33.3%; type IIIB in 8.3%; and type IIIC 5.2%; with respect to the right coronary artery, VIVID type I was found in 40.9%; type IIA in 24.7%; type IIB in 6.5%; type IIIA in 17.2%; type IIIB in 7.5%, and type IIIC in 3.2% of coronary arteries (Fig. 2). High-risk anatomy for coronary obstruction in either the LCA or the RCA according to the VIVID classification was

Table 3
Computed tomographic characteristics.

A	LCA (N = 96)	RCA (N = 93) ^a
Coronary height, mm	11.4 ± 5.2	13.8 ± 5.3
VTC, mm ^b	6.0 ± 2.3	5.2 ± 1.7
VTC < 4 mm, n (%)	12 (16.2)	11 (20.8)
VTSTJ, mm ^c	5.6 ± 2.5	5.1 ± 1.7
Narrow VTSTJ, n (%)	8 (19.5)	5 (21.7)
VIVID Classification using the cut-off of < 3.5 mm for VTSTJ, n (%)		
I	21 (21.9)	38 (40.9)
IIA	26 (27.1)	23 (24.7)
IIB	4 (4.2)	6 (6.5)
IIIA	32 (33.3)	16 (17.2)
IIIB	8 (8.3)	7 (7.5)
IIIC	5 (5.2)	3 (3.2)
Consider BASILICA, n (%)	17 (17.7)	16 (17.2)
VIVID Classification using the cut-off of < 2.5 mm for VTSTJ, n (%)		
I	21 (21.9)	38 (40.9)
IIA	26 (27.1)	23 (24.7)
IIB	4 (4.2)	6 (6.5)
IIIA	35 (36.5)	19 (20.4)
IIIB	8 (8.3)	7 (7.5)
IIIC	2 (2.1)	0
Consider BASILICA, n (%)	14 (14.6)	13 (14.0)
VIVID Classification only in stented valve (N = 84), n (%)		
I	17 (20.2)	32 (39.5)
IIA	26 (27.1)	23 (24.7)
IIB	4 (4.2)	6 (6.5)
IIIA	35 (36.5)	19 (20.4)
IIIB	8 (8.3)	7 (7.5)
IIIC	2 (2.1)	0
Consider BASILICA, n (%)	14 (14.6)	13 (14.0)

LCA = left coronary artery; RCA = right coronary artery; VIVID = Valve-in-Valve International Data; VTC = virtual valve to coronary ostium; VTSTJ = virtual valve to sinotubular junction.

^a 3 RCA could not be found.

^b VTC was assessed in type II and III.

^c VTSTJ was assessed in type IIIA and IIIC.

observed in 30 patients (31.3%) (Fig. 2). In a sensitivity analysis using a cut-off of < 2.5 mm for VTSTJ as proposed by the VIVID classification, high-risk anatomy in either the LCA or the RCA was observed in 25 patients (26.0%) (Table 3).

3.4. Procedural characteristics according to assigned VIVID classification

Procedural characteristics in patients evaluated for the risk of coronary obstruction are presented in Table 2. Coronary protection was performed in 7 patients (7.3%) as they were assumed at high-risk of coronary obstruction due to a low offtake of the coronary arteries and/or a shallow sinus of Valsalva as assessed by aortography and preprocedural MDCT: 5 (5.2%) had BASILICA (4 single BASILICA for left coronary cusp and 1 double BASILICA for left and right coronary cusps), and 2 (2.1%) had wire protection. Three patients were formally however not considered at high risk of coronary obstruction according to the VIVID classification. The types of VIVID classification in the 7 cases are shown in Table 4. Of the 30 patients with high-risk anatomy, coronary protection using wire protection or BASILICA was performed in 3 patients. No coronary obstruction occurred in any of the patients with high-risk anatomy according to the VIVID classification.

4. Discussion

The key findings of the present study can be summarized as follows. (1) In a prospective registry, coronary obstruction occurred in 2.9% of patients undergoing ViV-TAVI, and three in four obstructions occurred in patients with a stentless valve. (2) One-third of patients with a stented valve undergoing ViV-TAVI were deemed at high risk for coronary obstruction according to the VIVID classification. (3) Among patients with high-risk anatomy, coronary protection was performed in 10%. (4) Coronary obstruction occurred in none of the patients classified as high-risk patients according to the VIVID classification despite the absence of coronary protection.

Coronary obstruction is a rare but life-threatening complication of TAVI.^{13,23} The incidence of coronary obstruction following ViV-TAVI was

Table 4
VIVID classification in patients undergoing coronary protection.

	Implantetd bioprosthetic valve	Reason for ViV-TAVI	Types of coronary protection	VIVID type	
				LCA	RCA
Case 1	Stented valve with externally mounted leaflets	Bioprosthetic regurgitation	Coronary wire protection for LCA	IIA	I
Case 2	Sutureless valve	Bioprosthetic stenosis	Coronary wire protection for LCA	IIA	IIB
Case 3	Stented valve with internally mounted leaflets	Bioprosthetic stenosis	BASILICA	IIIA	IIIA
Case 4	Stented valve with externally mounted leaflets	Bioprosthetic stenosis	BASILICA	IIIA	IIB
Case 5	Stented valve with internally mounted leaflets	Bioprosthetic stenosis	BASILICA	IIIA	IIIA
Case 6	Stented valve with internally mounted leaflets	Bioprosthetic stenosis	BASILICA	IIIA	IIIC
Case 7	Stented valve with internally mounted leaflets	Bioprosthetic stenosis	BASILICA	IIIB	IIIA

6 cases underwent coronary protection did not have adequate MDCT image for assessment of the VIVID classification.

BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; LCA = left coronary artery; MDCT = multi-detector computed tomography; RCA = right coronary artery; ViV-TAVI = valve-in-valve transcatheter aortic valve implantation; VIVID = Valve-in-Valve International Data.

been reported as 2.0–3.5%,^{1,13,24} which is considerably higher than rates of coronary obstruction in TAVI for native aortic valve stenosis (<1%).²³ In line with previous studies, the incidence of coronary obstruction in the present study was 2.9%, and 3 out of 4 coronary obstructions occurred following ViV-TAVI in a stentless valve.^{13,25}

There are different mechanisms for coronary obstruction in ViV-TAVI procedures. In patients with low coronary off-take and a tubular shape of the sinus of Valsalva, coronary ostia can be directly obstructed by the leaflets of the bioprosthesis. Alternatively, coronary ostia can be obstructed indirectly by sinus sequestration in patients with a narrow and low sinotubular junction.

Dedicated risk assessment tools and methods for prevention have been proposed. A short VTC distance (<3–4 mm) has been suggested as an important predictor of coronary obstruction following ViV-TAVI based on data from the VIVID registry.¹³ Moreover, recent CT-based simulation analyses applied hypothesis-based criteria using a VTSTJ distance for the assessment of the risk of coronary obstruction due to sinus sequestration.²⁶ BASILICA is a promising, although technically demanding, technique to mitigate the risk of coronary obstruction among patients undergoing ViV-TAVI.²⁷ In a feasibility study and international registry, BASILICA was successful in 86.9–93.3%, and rates of coronary obstruction, death, and disabling stroke at 30 days were 0–4.7%, 2.8–3.3% and 0.5–3.3%, respectively.^{14,28,29}

The VIVID classification has been proposed to systematically assess the risk of coronary obstruction in ViV-TAVI for stented valves and to evaluate the need for BASILICA based on preprocedural MDCT.¹⁶ The present study is the first to evaluate the validity of the VIVID classification in a prospective registry and showed that coronary obstruction was rare even in patients with high-risk anatomy (VIVID type IIB, IIIB, or IIIC) and in the absence of coronary protection. The VIVID classification is a useful instrument to sensitize operators for coronary obstruction in a particular subset of patients planned for ViV-TAVI, and identifies anatomic constellations in which coronary protection may be warranted. While the classification provides a solid basis for the discussion of different treatment strategies, a tailored approach continues to be key, and the decision to perform coronary protection needs to be individualized. In addition, current algorithm does not take account for the procedural factor, including implantation depth and THV tilting. Multimodality imaging and 3D printing may be used to refine this process. Importantly the VIVID-classification is not applicable to patients with stentless valves who have the greatest risk of coronary obstruction with ViV-TAVI.

4.1. Study limitations

The findings of our study should be interpreted in light of several limitations. First, this is a single-center study, and the number of cases was relatively small. In turn, to our knowledge, our study is the first to validate the proposed algorithm in a dedicated Corelab. Second, although the risk of coronary obstruction was Core laboratory evaluated, more than 10% of patients were excluded from the CT analysis due to inadequate MDCT images. Furthermore, we did not routinely perform post-TAVI CT which would have allowed us to confirm the VTC and VTSTJ. Third, the results of the present study reflect the experience of a single high-volume center and may not be generalizable to other heart centers. Finally, the present study included only patients who underwent ViV-TAVI, resulting in selection bias. Due to its retrospective nature, the number of patients who were turned down for TAVI and underwent surgical aortic valve replacement or conservative management due to the risk of coronary obstruction were not available. Thus, the risk of coronary obstruction was likely underestimated.

5. Conclusion

Three in four coronary obstructions following ViV-TAVI occurred in patients with a stentless valve while none of the patients undergoing

ViV-TAVI for stented bioprostheses at high risk according to the VIVID classification had coronary obstruction. Refined tools are required to assess the risk of coronary obstruction, particularly for patients with stentless valves.

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None.

Declaration of competing interest

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